

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 42

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte ULF SCHRODER and LEIF G. SALFORD

Appeal No. 2000-2076
Application No. 08/481,131

HEARD: July 25, 2002

Before WINTERS, SCHEINER, and GREEN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 11, 12, 14, 15, and 19 through 36, which are all of the claims remaining in the application.

REPRESENTATIVE CLAIM

Claim 11, which is illustrative of the subject matter on appeal, reads as follows:

11. A method of contrast enhanced ultrasonic diagnostic imaging comprising: administering to a subject a contrast enhancing amount of spherical particles comprising a matrix of a biocompatible, biodegradable, non-immunogenic polymer enclosing a gaseous contrast agent which reflects sound waves, said polymer being selected from the group consisting of carbohydrates, carbohydrate derivatives and non-

polyamino acid synthetic polymers; and generating an ultrasonic image of said subject (emphasis added).

PRIOR ART

In rejecting the appealed claims under 35 U.S.C. § 112, first paragraph, the examiner does not rely on any prior art references.

THE REJECTION

Claims 11, 12, 14, 15, and 19 through 36 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a specification which does not provide adequate written descriptive support for the invention now claimed.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials:

- (1) the instant specification, including all of the claims on appeal;
- (2) the Edwards et al. article, referenced in the specification, page 3, line 10¹;
- (3) the Balinov Declaration, executed July 3, 1998, the Bernstein Declaration, executed May 9, 1997, the Church Declaration, executed May 15, 1998, the Myreng Declaration, executed August 24, 1999, and the Myreng Declaration, executed July 14, 1998;

¹ Edwards et al., "Scattering of Focused Ultrasound by Spherical Microparticles." J. Acoust. Soc. Am. Vol. 74, No. 3, pp 1006-1012 (September 1983).

- (4) applicants' Appeal Brief (Paper No. 29);
- (5) the Examiner's Answer (Paper No. 30); and
- (6) applicants' Reply Brief (Paper No. 31).

On consideration of the record, including the above-listed materials, we reverse the examiner's rejection under 35 U.S.C. § 112, first paragraph.

DISCUSSION

The PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in applicant's disclosure a description of the invention defined by the claims. In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). In an effort to discharge that burden here, the examiner focuses on the language "a gaseous contrast agent" in claim 11.² According to the examiner, the specification as filed does not describe spherical particles comprising a matrix of a biocompatible, biodegradable, non-immunogenic polymer enclosing a gaseous contrast agent which reflects sound waves. Therefore, the examiner argues, applicants' claims do not enjoy adequate, written descriptive support in the specification, as filed, and they run afoul of the written description requirement in 35 U.S.C. 112, first paragraph. We disagree.

The language "a gaseous contrast agent" is not found verbatim in the original disclosure. However, in order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the

² Independent claim 11 was amended in its current form in Paper No. 8, received July 3, 1996.

claimed subject matter at issue. Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000). Nor does the original disclosure have to contain a working example or embodiment illustrating the limitation at issue. Rather, the test is whether applicants' specification, as filed, reasonably conveys to the artisan that the inventors had possession at that time of the later claimed subject matter. Vas-Cath Inc. v Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Any person skilled in the art, reading the original disclosure, must "immediately discern the limitation at issue" in the claims. Waldemar Link GMBH & Co. v. Osteonics Corp., 32 F.3d 556, 558, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994). The inquiry is factual, and must be assessed on case-by-case basis. See Vas-Cath Inc. v. Mahurkar, 935 f.2d at 1561, 19 USPQ2d at 1116.

We have carefully reviewed the declaration evidence in this case, including the Balinov Declaration executed July 3, 1998.³ According to Dr. Balinov, applicants' original disclosure describes spherical particles comprising a polymeric matrix enclosing a contrast agent, e.g., an ultrasound contrast agent. In this regard, Dr. Balinov points to original claim 4 describing a "contrast agent [which] reflects sound waves."

The question is would any person skilled in the art have understood what would be an appropriate material for the ultrasound contrast agent described in the original disclosure? Dr. Balinov answers that question in the affirmative, stating that:

³ The examiner has challenged Dr. Balinov's qualifications (Examiner's Answer, Paper No. 30, page 10, first complete sentence). However, having reviewed the educational background and research experience set forth at page 1 of the Balinov Declaration, we believe that Dr. Balinov is qualified to interpret applicants' specification, and that the Balinov Declaration is entitled to weight in this ex parte proceeding.

8. For such particulate ultrasound contrast agents, the most relevant property for achieving contrast enhancement would have been understood to be compressibility as this is the property which allows ultrasound energy to be absorbed and reemitted, ie. “reflected”, to use the word used in claim 4 of the published text. The material used as the ultrasound contrast agent must react to pressure, ie. compress, much like a spring, converting sound energy to potential energy, and then it must release that energy as ultrasound.

9. Simply put, while the contrast agent could be solid, a liquid or a gas, since the compressibility of a gas is so much greater than that of a solid or liquid, the person skilled in the field of ultrasound and understanding the physical nature of dispersions at the priority date would have been in no doubt that the first choice of an ultrasound contrast agent (for enclosure in a matrix in accordance with claim 4 of the published text) would have been a gas, or more particularly a gas bubble. [Balinov Declaration, paragraphs 8 and 9, emphasis added]

Couched in terms of the case law, Balinov’s Declaration supports a finding that (1) applications’ specification, as filed, reasonably conveys to the artisan that the inventors had possession at that time of the later claimed subject matter; and (2) any person skilled in the art, reading the original disclosure, would “immediately discern” the limitation at issue in the claims.

All in all, we believe that the weight of the evidence supports a finding that “a gaseous contrast agent” recited in claim 11 enjoys adequate, written descriptive support in applicants’ original disclosure. On the strength of the Balinov Declaration, we reverse the examiner’s rejection of claims 11, 12, 14, 15, and 19 through 36 under 35 U.S.C. § 112, first paragraph, for lack of adequate written description in the specification as filed.⁴

⁴ Our reversal is not predicated on the Edwards et al. article, referenced at page 3, first full paragraph of the specification; on applicants’ summary of that article, added by way of amendment in Paper No. 18, received October 14, 1997; or on any argument pertaining to Edwards et al. The issue whether material added to the specification, page 3, first full paragraph, constitutes new matter, is severable from the issue on appeal. The former issue is petitionable, not appealable. See the Examiner’s Answer (Paper No. 30), paragraph bridging pages 5 and 6.

The examiner also argues that the abstract accompanying Paper No. 18, received October 14, 1997, constitutes new matter and must be cancelled. See the Examiner's Answer (Paper No. 30), paragraph bridging pages 5 and 6. This issue is inextricably linked to the examiner's rejection of claims under 35 U.S.C. § 112, first paragraph. Where, as here, both the claims and specification are said to contain new matter, directly or indirectly, and there has been a rejection and objection by the examiner, the issue becomes appealable and should not be decided by petition. See MPEP § 2163.06 II. For reasons already discussed, we find that the abstract accompanying Paper No. 18, received October 14, 1997, does not constitute new matter.

The examiner's decision is reversed.

REVERSED

Sherman D. Winters
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

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